EUROPEAN COMMISSION

Brussels, 12.1.2010
C(2010)119

COMMISSION DECISION

of 12.1.2010

amending, for the purposes of its extension, the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION DECISION

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amending, for the purposes of its extension, the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application(s) for extension within the meaning of Annex II to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], submitted by Sanofi-Aventis Deutschland GmbH on 28 January 2009, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 October 2009,

Whereas:

(1) The medicinal product "Apidra - Insulin glulisine", entered in the Community register of medicinal products under the numbers EU/1/04/285/001-004 and authorised by Commission Decision C(2004)3653 of 27 September 2004, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) The amendments requested should therefore be granted.

(3) Decision C(2004)3653 should therefore be amended accordingly,

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 159, 27.6.2003, p. 24.
3 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 12.1.2010

For the Commission
Heinz ZOUREK
Director-General